K080620

Premarket Notification (510(k)) Summary

1. Sponsor Information:

MAY 19 2008

3M Health Care
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

Contact Person: Maria Ruiz
Senior Regulatory Affairs Associate
Phone Number: (651) 736-2733
FAX Number: (651) 737-5320

Date of Summary: April 18, 2008

2. Device Name and Classification:

Common or Usual Name: Antimicrobial I.V. Securement Dressing

Proprietary Name: 3M™ Tegaderm™ CHG Dressing
(Chlorhexidine Gluconate I.V. Securement Dressing)

Classification Name: Antimicrobial Dressing, Unclassified

Performance Standards: None

3. Predicate Devices:

- 3M™ Tegaderm™ CHG Dressings (K063458, cleared April 5, 2007)
- Bioclusive Transparent Film Dressing (K895207, cleared September 28, 1989)
- Opsite IV 3000 (K895353, cleared December 14, 1989)
- Tegaderm™ Transparent Film Dressings (K973036, cleared November 12, 1997)
- SorbaView® Ultimate Window Dressing
- SorbaView® 2000

4. Description of Device:

3M™ Tegaderm™ CHG Dressing, Chlorhexidine Gluconate I.V. Securement Dressing, is used to cover and protect catheter sites and to secure devices to skin. Available in a variety of shapes and sizes to meet the needs of the caregiver.

Tegaderm™ CHG Dressing consists of a transparent adhesive dressing and an integrated pad containing Chlorhexidine Gluconate (CHG), a well-known antiseptic agent with broad-spectrum antimicrobial and antifungal activity. The dressing is a barrier to liquid (waterproof), bacteria and viruses* and yeast, and

protects the IV site from outside contamination. The pad absorbs up to eight times its weight in fluid. *In vitro* testing (log reduction, barrier, and zone of inhibition) demonstrates that the Tegaderm™ CHG dressing has an antimicrobial effect against, and is a barrier to, the passage of a variety of gram-positive and gram-negative bacteria and yeast in the dressing. Tegaderm™ CHG Dressing is transparent, allowing continual site observation, and is breathable, allowing good moisture vapor exchange.

**In vitro* testing has proven that Tegaderm CHG provides a viral barrier from viruses 27 nm in diameter, (e.g. HCV) or larger (e.g. HBV and HIV) while the dressing remains intact without leakage.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 2008

3M Health Care
% Ms. Maria Ruiz
Senior Regulatory Affairs Associate
3M Center, Building 275-5W-06
St. Paul, Minnesota 55144-1000

Re: K080620
Trade/Device Name: 3M™ Tegaderm™ CHG Dressing, (Chlorhexidine Gluconate I.V. Securement Dressing)
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 18, 2008
Received: April 22, 2008

Dear Ms. Ruiz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K080620

Device Name: 3M™ Tegaderm™ CHG Dressing,
(Chlorhexidine Gluconate I.V. Securement Dressing)

Indications for Use:

3M™ Tegaderm™ CHG Dressings (Chlorhexidine Gluconate I.V. Securement Dressing), can be used to cover and protect catheter sites and to secure devices to skin. Common applications include IV catheters, other intravascular catheter and percutaneous devices.

Prescription Use X OR Over-The-Counter-Use ____
(Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for MXR

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K080620